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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,916	03/31/2004	Masakazu Takahashi	251165US0	5710

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT	PAPER NUMBER
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1638

NOTIFICATION DATE	DELIVERY MODE
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10/05/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/812,916

Applicant(s)

TAKAHASHI ET AL.

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 11 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 24, 2007 has been entered.

2. Applicant's amendment of claims 1, 11, 14 and 18 and cancellation of claims 6-10, 12, 13, 19 and 20, filed July 24, 2007, have been received and entered in full.

3. Claims 1-5, 11 and 14-18 are under examination.

Claim Rejections - 35 USC § 112, first paragraph – Written Description

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-5, 11 and 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are broadly drawn to any soybean genetically lacking all subunits of β -conglycinin and glycinin and wherein the soybean has a total free amino acid content in the seed thereof that is higher than

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the content in the seeds of any of Fukuyutaka and Tachiyutaka having all subunits of β -conglycinin and glycinin, Enrei lacking only $A_5A_4B_3$ subunit of glycinin, Kyukei 305 lacking all subunits of β -conglycinin and EnB1 lacking all subunits of glycinin that are cultivated under similar conditions.

Applicant argues that fact that the subunits were known, the specification and claims satisfy the written description requirement because once one knows the structure, one can generate a soybean lacking or not expressing those known sequences (see page 6, last paragraph to page 7, lines 1-6 of 'Remarks' filed July 24, 2007)..

This is not persuasive. The rejection is not based on the fact that the subunits were known and is based on the lack of description and possession in the specification regarding the broad genus of soybeans having the claimed characteristics. The specification only provides an adequate written description for soybean lines QF2F₃-1, QF2F₃-2 and QF2F₃-3 (see page 11 and page 12, Table 1).

See MPEP 2163(I) where it states "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116".

The specification only provides evidence that Applicant was in possession of soybean lines QF2F₃-1, QF2F₃-2 and QF2F₃-3 (see page 11 and page 12, Table 1) and

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not each and every soybean plant having the claimed characteristics as is broadly claimed.

Also see MPEP 2163.02 where it states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.'" In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)".

In the instant invention, one of ordinary skill in the art would only recognize that Applicant has invented has only invented soybean lines QF2F₃-1, QF2F₃-2 and QF2F₃-3 (see page 10, Example 1 to page 11).

MPEP 2163.02 further states, "[u]nder *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed".

In the instant case, Applicant has conveyed with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicant was in possession of soybean lines QF2F₃-1, QF2F₃-2 and QF2F₃-3 (see page 11 and page 12, Table 1) and not each and every soybean plant having the claimed characteristics as is broadly claimed. See *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears

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of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

Thus, based on the disclosure of the specification, Applicant has only described and shown possession of soybean lines QF2F₃-1, QF2F₃-2 and QF2F₃-3.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

Claims 1-5, 11 and 14-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for soybean lines QF2F₃-1, QF2F₃-2 and QF2F₃-3, does not reasonably provide enablement for the broad genus of soybean seed having the claimed characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The specification fails to provide any guidance for the broad genus of soybean seed having total free amino acid content in the seed that is higher than the content of other soybean seed with regards to their genetic, morphological and/or physiological

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characteristics. The specification only provides guidance for soybean lines QF2F₃-1, QF2F₃-2 and QF2F₃-3 (see page 11 and page 12, Table 1).

The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern, US Patent 5,850,009, column 4, lines 41-46).

Eby et al (U.S. Patent No. 6,670,530, December 30, 2003) teach, "[t]he cultivars which are developed are unpredictable [and] [t]his unpredictability is because the breeder's selection occurs in unique environments, with no control at the DNA level...and with millions of different possible genetic combinations being generated [thus a] breeder of ordinary skill in the art cannot predict the final resulting lines he develops, except possibly in a very gross and general fashion" (see column 2, lines 18-27). Thus, one of skill in the art would not be able to make and use the claimed invention because it is unpredictable to produce the exact same plant even when crossing with the same starting material.

Given the lack of guidance regarding the broad genus of soybean plants that have the claimed characteristics, the relative lack of skill of those in the art in developing the exact same cultivar even when using the same starting materials, the unpredictability of the art in producing the exact same cultivar using the same starting materials, and the breadth of the claims, it would require one skilled in the art undue trial and error experimentation to make and use the invention as it is broadly claimed.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-5, 11 and 14-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Takahashi et al (Planta 217: 577-586, 2003, published online 2 April 2003). The claims read on any soybean genetically lacking all subunits of β -conglycinin and glycinin and wherein the soybean has a total free amino acid content in the seed thereof that is higher than the content in the seeds of any of Fukuyutaka and Tachiyutaka having all subunits of β -conglycinin and glycinin, Enrei lacking only A₅A₄B₃ subunit of glycinin, Kyukei 305 lacking all subunits of β -conglycinin and EnB1 lacking all subunits of glycinin that are cultivated under similar conditions.

Takahashi et al disclose a soybean line, namely 'QF2', lacking both β -conglycinin and glycinin components (see, for example, page 578, 2nd column, 'Materials and methods'; page 579, Figure 1 and Table 1).

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property,

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then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Conclusion

8. No claims are allowed.

Contact Information

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is (571) 272-2918. The examiner can normally be reached Monday – Friday, 7:30 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Keith O. Robinson, Ph.D.

September 26, 2007

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, reading "David H. Kruse". The signature is written in a cursive style with a large, looping initial "D" and "K".